Treadwell Therapeutics Announces A Presentation at the 2022 SITC Annual Meeting Featuring a Clinical Trial Update on CFI-402411, a First-in-Class HPK1 inhibitor

Description

NEW YORK, Nov. 11, 2022 /PRNewswire/ â?? Treadwell Therapeutics, a clinical-stage biotechnology company developing novel medicines cancer, today announced a presentation for CFI-402411, an oral, first-in-class inhibitor of Hematopoietic Progenitor Kinase 1 (HPK1), a negative regulator of immune cell activation, at the 37th Society for Immunotherapy of Cancer (SITC) Annual Meeting being held virtually and in-person from November 8-12, 2022 at the Boston Convention and Exhibition Center in Boston, MA. This presentation will provide an interim update from the ongoing TWT-101, a Treadwell-sponsored, first in human study of CFI-402411 in advanced solid tumors.

â??Inhibition of HPK1 with CFI-402411 could represent a safe and effective means to stimulate anti-tumor immunity. We continue to observe good tolerability and emerging signs of clinical activity, including in patients that have failed anti-PD1 therapyâ?• said Dr. Omid Hamid, Chief of Research/ Immuno-Oncology at The Angeles Clinic & Research Institute, a Cedars-Sinai affiliate, Los Angeles, California.

â??We are encouraged by the emerging clinical profile of CFI-402411,â?• said Dr. Michael Tusche, co-Chief Executive Officer at Treadwell Therapeutics. â??We hope to define the Recommended Phase 2 dose for the molecule in the near term and are excited about the next stage of development for CFI-402411 both as a monotherapy and in combination with checkpoint blockade.â?•

2022 SITC Poster Presentations and Details

TWT-101: A First-In-Clinic, Phase 1/2 Study Of CFI-402411, a Hematopoietic Progenitor Kinase-1 (HPK1) Inhibitor, as a Single Agent and in Combination with Pembrolizumab in Subjects with Advanced Solid Malignancies
Publication Number: 750
Poster Hall
Date and Time: November 11, 2022, 7:00 am â?? 8:30 pm

In the presentation titled, â??TWT-101: A First In-human, Phase 1/2 Study of CFI-402411, Hematopoietic Progenitor Kinase-1 (HPK1) Inhibitor, as a single agent and in combination with pembrolizumab in subjects with advanced solid malignancies,â?• CFI-402411 demonstrated a clinically manageable safety profile at doses up to 560 mg QD with exposures increasing proportionately with dose. In the efficacy evaluable population (N=31), 2 patients achieved partial response as best response. Both of responses were in Head and Neck Squamous Cell Carcinoma (HNSCC) patients previously treated with pembrolizumab. One patient was treated as a monotherapy (400 mg) and the other treated in combination (60 mg + pembrolizumab) with 36% and 81% reduction in target lesions, respectively. Nine patients had best response as stable disease and stayed on study for at least 4 cycles. The most common treatment emergent toxicities of any grade, which occurred in greater than 10% of patients, were diarrhea (61%), fatigue (39%), nausea (33%), decreased appetite (30%), vomiting (26%), dehydration (17%), ALT increase (15%). dyspepsia (15%) and back pain (11%).

About CFI-402411

CFI-402411 is a highly potent inhibitor of HPK1, which in preclinical studies has been shown to have an immune-activating effects including the alleviation of inhibition of T cell receptors (TCR), disruption of abnormal cytokine expression, alteration of the tumor immunosuppressive environment through effector cells (i.e. Regulatory T cells or Treg), and potent anti-leukemic effects in several mouse models.

About TWT-101

TWT-101 is a Phase 1/2 clinical trial of CFI-402411 in advanced solid malignancies. The study is designed to assess the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of CFI-402411, as well as to determine optimal dosing as a monotherapy and in combination with the anti-PD1 antibody, pembrolizumab. The trial could enroll up to 170 patients at up to 15 sites in North America and Asia. It will involve 5 arms including monotherapy and combination dose escalation and expansion in a variety of tumor types, as well as biomarker backfills.

About Treadwell Therapeutics

Treadwell Therapeutics is a science driven, clinical-stage multi-modality oncology company. The company is developing first-in-class and best-in-class medicines to address unmet needs in patients with cancer. The Companyâ??s robust, internally developed pipeline includes a first-in-class PLK4 kinase inhibitor, CFI-400945 and a best-in-class TTK inhibitor, CFI-402257, and CFI-402411. Treadwell also has a rapidly advancing pre-clinical pipeline with multiple biologic and next generation TCR based autologous cell therapy programs. For more information, please visit www.treadwelltx.com.

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